

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1-45. (Canceled)

46. (Currently Amended) ~~The A~~ freeze-dried formulation of claim 24 consisting of:

a follicle-stimulating hormone or a variant thereof, a luteinising hormone or a variant thereof, at least one surfactant selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate, and polyoxyethylene (20) sorbitan monooleate, a stabilizer and tonicity agent selected from the group consisting of monosaccharides, disaccharides and sugar alcohols, an antioxidant, and a phosphate buffer.

47. (Previously Presented) The freeze-dried formulation of claim 46 consisting of recombinant human follicle-stimulating hormone, recombinant human luteinising hormone, polyoxyethylene (20) sorbitan monolaurate, sucrose, methionine, and a phosphate-buffer.

48. (Previously Presented) The freeze-dried formulation according to claim 47 including: 0.1-10 µg/mg recombinant human follicle-stimulating hormone, 0.1-3 µg/mg recombinant human luteinising hormone, and 0.001-0.1 mg/mg polyoxyethylene (20) sorbitan monolaurate, based on the weight of the formulation.

49. (Previously Presented) The freeze-dried formulation according to claim 48 in which the relative weight amounts of the components comprise 12.0 µg of recombinant human follicle-stimulating hormone, 3.7 µg of recombinant human luteinising hormone, 30.0 mg of sucrose, 0.05 mg of polyoxyethylene (20) sorbitan monolaurate and 0.1 mg of methionine.

50. (Currently Amended) An article of manufacture comprising:

a first container filled with a freeze-dried formulation consisting of a recombinant, human follicle-stimulating hormone or a variant thereof, a recombinant, human luteinising hormone or a variant thereof, polyoxyethylene (20) sorbitan monolaurate, sucrose, methionine; and a phosphate buffer, according to claim 24; and

a second container that comprises a solvent for reconstitution.

51. (Currently Amended) An article of manufacture according to claim 50, wherein the second container contains water for reconstitution.

52-54. (Canceled)

55. (Currently Amended) A method for manufacturing a freeze-dried formulation according to claim 24, comprising:

forming a mixture consisting essentially of a follicle-stimulating hormone or a variant thereof, a luteinising hormone or a variant thereof, at least one surfactant selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate, and polyoxyethylene (20) sorbitan monooleate, a stabilizer and tonicity agent selected from the group consisting of monosaccharides, disaccharides and sugar alcohols, an antioxidant, and a phosphate buffer; and

subjecting the mixture to lyophilization.

56. (Currently Amended) The method according to claim 55, wherein the mixture contains consists of recombinant human follicle-stimulating hormone, recombinant human luteinising hormone, sucrose, polyoxyethylene (20) sorbitan monolaurate and methionine.

57. (Currently Amended) The method according to claim 56, wherein the mixture
~~contains~~consists of component amounts to yield a freeze-dried formulation containing
0.1-10 µg/mg recombinant human follicle-stimulating hormone, 0.1-3 µg/mg recombinant human
luteinising hormone, and 0.001-0.1 mg/mg polyoxyethylene (20) sorbitan monolaurate, based on the
weight of the formulation.

58. (Currently Amended) The method according to claim 57, wherein the mixture
~~contains~~consists of component amounts to yield relative weight amounts of the
components in the freeze-dried formulation comprising 12.0 µg of recombinant human
follicle-stimulating hormone, 3.7 µg of recombinant human luteinising hormone, 30.0 mg of
sucrose, 0.05 mg of polyoxyethylene (20) sorbitan monolaurate and 0.1 mg of methionine.

59. (New) The article of manufacture of claim 50 in which the first container is
filled with a freeze-dried formulation consisting of recombinant human follicle-stimulating
hormone, recombinant human luteinising hormone, polyoxyethylene (20) sorbitan monolaurate,
sucrose, methionine, and a phosphate-buffer.

60. (New) The freeze-dried formulation of claim 46 in which the biological activity of
the FSH and of the LH is well conserved after nine months of storage.